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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,724	01/26/2004	Thomas Grupp	HOE-795	2534
20028	7590	02/18/2005	EXAMINER	
Lipsitz & McAllister, LLC 755 MAIN STREET MONROE, CT 06468			SHAW, SHAWNA JEANNINE	
			ART UNIT	PAPER NUMBER
			3737	

DATE MAILED: 02/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/765,724	GRUPP ET AL.	
	Examiner	Art Unit	
	Shawna J. Shaw	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/26/2004, 6/16/2004, 12/30/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 7-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 6 and 14-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06162004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of species A in the reply filed on 12/30/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Although applicant has indicated that claims 1-6 and 14-25 read on the elected species, the examiner believes that claim 4 (directed to a radiation-reflecting coating) does not read on species A, but rather on species C (and notes that claim 8 further addressing the radiation-reflecting coating of claim 4 was not elected). Thus, for examination purposes, the examiner has treated claims 1-3, 5, 6 and 14-25 as directed to elected species A.

Priority

2. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Claim Objections

3. Claims 1, 2 and 18 are objected to because of the following informalities: In claim 1, "the glass fibers" lack positive antecedent basis. In claim 2, it is unclear how glass fibers of the elected species (having a Bragg grating) are distributed over the entire extent of the implant. In claim 18, "the transformer" lacks antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 14-20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Regarding claims 14-20, the specification does not adequately teach how to [directly] connect the at least one glass fiber (in the form of a fabric or fleece) to the measuring device or transducer (especially where the measuring device is external to the body). Regarding claim 24, the specification does not adequately disclose what wavelengths and intensities are chosen to induce mechanical and/or material changes in the implant.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dry (5,989,334) in view of Kobayashi et al. of record.

Regarding claims 1, 2 and 5, Dry discloses "smart" fiber-reinforced matrix materials for use in bone replacements and prosthetic devices (col. 12 lines 23-56, col. 20 lines 54-62). Although Dry discloses glass fibers (col. 9 lines 5-19) that may be woven (col. 9 lines 9-11) into a fabric (col. 13 lines 44-45, col. 14 lines 5-6), Dry does not explicitly disclose glass fiber fabrics embedded in the bone replacements or prosthetic devices. Kobayashi et al. demonstrates it is well known to use of glass fiber fabrics distributed throughout bone implants/prosthetics for their properties of biocompatibility, strength and conformability (Kobayashi et al., col. 3 lines 33-54 and col. 4 lines 17-25 and 58-63; and as also evidenced by Serhan et al. [0091]). It would have therefore been obvious at the time the invention was made to a person of ordinary skill in the art to use the fiber reinforcement materials of Dry in the form of glass fiber fabrics as taught by Kobayashi et al. for the above described reasons and as is well known in the art. In addition, it would have further been obvious at the time the invention was made to a person of ordinary skill in the art to pair, or couple, the glass

fibers with optical sensor fibers as additionally taught by Dry (col. 9 lines 43-48) to "monitor" or "meter" physical parameters such as strain, temperature or displacement which are particular to the integrity of the joint/prosthesis as is known in the art (as evidenced by Ishikawa et al. col. 7 lines 10-28), and particular to tactile bio-feedback (as evidenced by Lyons, [0014]) - and further wherein optical sensing of such parameters is well known (as evidenced by Farahi [0094-95]; Chin et al., col. 23 lines 3-12; and Rosenberg, col. 1 lines 23-32).

6. Claims 3, 6, 14, 15, 21-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dry (5,989,334) in view of Kobayashi et al. of record as applied to claim 1 above and further in view of Lyons (2004/0146235).

Regarding claims 3, 6, 14, 15, 21-23 and 25, Dry and Kobayashi et al. differ from the claimed invention in that an optical fiber for feeding electromagnetic energy into the implant and directly connected to the measuring device is not specifically addressed. Dry and Kobayashi et al. also do not disclose a Bragg grating. Lyons teaches "intelligent" prosthetic structures which direct light from miniature lasers into the implant via glass (i.e., silica) fibers to obtain accurate and highly-localized measurements of strain and/or temperature as distributed over the device [0014]. Lyons also discloses wherein the optical fibers comprise sensors in the form of Bragg gratings [0034]. Lyons further discloses wherein the optical fibers are directly connected to an implantable microprocessor (fig. 2, element 70). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to incorporate the glass fiber sensors of Lyons into the prosthesis/implant of Dry in view of Kobayashi to obtain

highly-localized strain and temperature measurements therein, thereby providing accurate bio-feedback and/or device integrity data in substantially real-time.

7. Claims 3 and 14-20, are rejected under 35 U.S.C. 103(a) as being unpatentable over Dry (5,989,334) in view of Kobayashi et al. of record as applied to claim 1 above and further in view of Nurmikko et al. (2004/0015211).

Regarding claims 3, Dry and Kobayashi et al. differ from the claimed invention in that a measuring device that feeds electromagnetic energy into the implant is not specifically addressed. Nurmikko et al. disclose feeding electromagnetic radiation into a sensor element for prosthetic control and/or therapy (fig. 4A and 4B, [0043, 44]). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to feed electromagnetic energy into the sensor element or implant as taught by Nurmikko et al. in the invention as taught by Dry in view of Kobayashi et al. to selectively activate the sensor during certain times (thereby saving energy) and/or to provide controlled therapy.

Regarding claims 14 and 15, Dry and Kobayashi et al. differ from the claimed invention in that an optical fiber directly connected to an implantable microcontroller is not specifically addressed. Nurmikko et al. disclose optical fibers directly connected to an implantable microcontroller (100, figures 3A-D). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to directly connect the optical sensor fiber(s) of Dry in view of Kobayashi to an implantable controller/sensor as taught by Nurmikko et al. to provide a self-contained means for prosthetic control and/or therapy with reduced possibility of infection.

Regarding claims 16-20, Dry and Kobayashi et al. differ from the claimed invention in that an optical fiber connected to a transducer or transformer for communicating signals via a non-physical connection is not specifically addressed. Nurmikko et al. teaches optical fibers and implants for prosthetic control and/or therapy including transforming between electrical and optical signals, and wirelessly communicating with an external controller [0038-40], [0044]. It would have been obvious at the time the invention was made to a person of ordinary skill in the art to convert between optical and electrical signals and provide wireless telemetry thereof as taught by Nurmikko et al. in the invention as taught by Dry in view of Kobayashi et al. to provide a non-invasive means for communicating with the internal device and interfacing with an external controller.


Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (571) 272-4743. The examiner can normally be reached on 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shawna J. Shaw
Primary Examiner
Art Unit: 3737
02/11/2005